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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,704	12/30/1999	SUSAN W. BARNETT	1631.002	6738

27476 7590 04/25/2008

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EXAMINER	
PITRAK, JENNIFER S	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
04/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/475,704	BARNETT ET AL.	
	Examiner	Art Unit	
	JENNIFER PITRAK	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-10,24-43,49-60,63-66 and 68-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *68-75* is/are allowed.

6)☒ Claim(s) *2,4,7-10,24-43,49-60 and 63-66* is/are rejected.

7)☒ Claim(s) *5 and 6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Remarks

Applicants amended claims 2 and 4 in the response filed 01/25/2008, obviating the rejections under 35 U.S.C. § 102(b) and § 103(a). Applicants filed terminal disclaimers disclaiming the terminal part of any patent granted on the instant application that would extend beyond the expiration date of U.S. Patent Nos. 6,602,705 and 7,211,659. These terminal disclaimers obviate the rejections under nonstatutory obviousness-type double patenting.

Claims 2, 4-10, 24-43, 49-60, 63-66, 68-75 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any rejections set forth or reiterated in this Office Action are those that are outstanding.

Claim Rejections - 35 USC § 112

Claims 2, 4, 7-10, 24-43, 49-60, and 63-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is **maintained** for the reasons of record and as further clarified.

The claims are to an expression cassette comprising a nucleotide sequence having at least 90% sequence identity to full-length SEQ ID NO:3 (claim 2) or full-length SEQ ID NO:4 (claim 4) and which encodes an immunogenic HIV *Gag* polypeptide that elicits a *Gag*-specific immune

response. The claims embrace a genus of compounds having 90% identity with either SEQ ID NO: 3 or 4. It is well within the level of skill in the art to determine whether a sequence has 90% sequence identity with SEQ ID NO: 3 or 4 and whether such compounds are described is not in dispute. However, the claimed invention has a second requirement: that the polynucleotide encodes an immunogenic HIV Gag polypeptide that elicits a Gag-specific immune response. It is the genus of compounds that are both 90% identical to SEQ ID NOs: 3 or 4 and also fulfill this second requirement that do not satisfy the written description requirement.

As applicants themselves have noted during the course of prosecution, of the many and varied embodiments of polynucleotides with at least 90% sequence identity to SEQ ID NOs: 3 or 4, not all of them will elicit a Gag-specific immune response. The specification does not adequately describe which nucleotide sequences with at least 90% sequence identity to SEQ ID NO: 3 or SEQ ID NO: 4 also fulfill the second requirement of encoding polypeptides that elicit a Gag-specific immune response. While the specification describes that SEQ ID NOs: 3 and 4 in their entirety encode immunogenic Gag polypeptides, which polynucleotides having less than 100% identity with these sequence encode polypeptides that elicit a Gag-specific immune response are not known nor are they described. Example 4 of the instant specification describes a method for determining which nucleotide sequences with at least 90% sequence identity to SEQ ID NO: 3 or SEQ ID NO: 4 elicit a Gag-specific immune response. However, this teaching of how to identify the invention is not a description of the invention. The MPEP Chapter 2163 states:

> Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the

> applicant was in possession of the claimed invention. See, e.g., Pfaff v. WellsElecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

The claims and specification do not describe the embodiments of sequences with 90% - 100% sequence identity to SEQ ID NOs: 3 or 4 that elicit a Gag-specific immune response. The specification does not yield guidance as to the structure, such as where within SEQ ID NOs: 3 or 4 are found the essential sequences that provide the function of encoding a Gag polypeptide that will be immunogenic such that one of skill in the art would be apprised of which nucleotides can or cannot be varied, in order to provide the claimed function of eliciting a Gag-specific immune response. Thus, the claims are not adequately described because the specification lacks both a reduction to practice and drawings, formulas, or distinguishing characteristics, such as sequences or regions of sequence conservation, that show the claimed invention was complete.

Response to Arguments

Applicants' arguments regarding the written description rejection have been fully considered but they are not persuasive.

Applicants argued on page 9 of their 01/25/2008 response that the claims are drawn to nucleotides that encode Gag polypeptides that elicit a Gag-specific immune response and, therefore, the claims do not encompass polynucleotides encoding polypeptides that elicit a non-specific immune response and that therefore the claims are adequately described. The examiner agrees that the claimed invention is limited to those nucleotides that are both 90% identical to SEQ ID NOs: 3 or 4 and have the function of encoding an immunogenic Gag polypeptide. The

examiner further agrees that polynucleotides encoding polypeptides that elicit a non-specific immune response are not embraced by the instant claims. However, this is not persuasive for the reasons stated in the above rejection, namely that while those polynucleotides meeting the structural limitations (at least 90% identity to SEQ ID NOs: 3 and 4) are described, those which additionally meet the functional limitation of eliciting a Gag-specific immune response are not described. Applicants point to Example 4 of the specification as providing a description of the claimed polynucleotides encoding Gag polypeptides that generate a Gag-specific immune response. Contrary to this assertion, and as described above, Example 4 describes a method of how to find the claimed polynucleotides, but does not describe the polynucleotides. Because one of skill in the art of skill in the art would not be able to envisage which polynucleotides having 90% identity with SEQ ID NOs: 3 or 4 encode immunogenic Gag polypeptides and which do not, the genus of compounds embraced by the claims is not adequately described.

Allowable Subject Matter

Claims 5 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 68-75 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak, PhD
Examiner
Art Unit 1635

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635